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10/687,636	10/20/2003	Patrick Rambaud	0501-1017-1	1794

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EXAMINER	
WHALEY, PABLO S	

ART UNIT	PAPER NUMBER
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/687,636	RAMBAUD, PATRICK	
	Examiner	Art Unit	
	PABLO WHALEY	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,3, 6, 7, 11-18,20-22,25 and 27-34* is/are pending in the application.

4a) Of the above claim(s) *3,6,7,11-14,22 and 27-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,15-18,20,21,25 and 30-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims Under Examination

Claims 1, 2, 15-18, 20-21, 25, and 30-34 are under examination. Claims 32-34 are newly added. Claims 4-5, 8-10, 19, 23-24, and 26 are cancelled. Applicant's election of Species I-A (cells collected from human), II-(i) (status-characterizing information obtained from blood sample measurements), III-A (bioelectronic information), and IV-C in the response filed 3/15/2006 is again noted. Claims 3, 6, 7, 11-14, 22, and 27-29 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention or species, there being no allowable generic or linking claim.

Withdrawn Rejections

The rejection of claims 1, 2, 4, 5, 8-10, 15-21, 23-25, and 30-31 under 35 U.S.C. 112, first paragraph, for lack of enablement is withdrawn in view of applicant's amendments, filed 11/16/2007, which cancelled limitations drawn to "determining parameters of a deferred use protocol."

The rejection of claims 1, 2, 4, 5, 8-10, 15-21, 23-25, and 30-31 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicant's amendments, filed 11/16/2007.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 15-18, 20, 25, and 30-33 are rejected under 35 U.S.C. 102 (a) as being anticipated by Lefesvre et al. (WO/1999/053030; Publication Date: 10/21/1999, p.1-5). Claims 32-33 are newly added and rejected as necessitated by amendment.

Lefesvre et al. teach a method and system for management of batches of immuno-qualified cells, in particular of lymphocytes (i.e. immunocompetent cells) or monocytes, for differed uses [Abstract]. Lefesvre et al. [Fig. 1] teach the following aspects of instant claims 1, 30, 31, and newly added claims 32 and 33: Means for preserving cells (e.g. deep freezing), multiple storage centers, means for patient data collection (i.e. identification), means for storing data comprising lymphocyte data from multiple batches, means for collecting information characteristic of the status of health of a subject, means for therapeutic indication for re-use, means for receiving a request for batches for re-use, and a cell treatment center.
Lefesvre et al. also teach the following aspects of the instantly claimed invention: personal libraries for patients personal library preserving a sum of immunizing information stored in the taken immuno-qualified cells, and, response to a treatment; a treatment of whole or part of the immunizing information accumulated in the aforementioned personal library, and localization of one or more stored batches of immuno-qualified cells, followed by a transfer of this or these batches towards a cellular processing center requiring (i.e. expert system) [p.2, ¶ 2], as in claims 1 and 25. Lefesvre also teach the transfer of data and parameters directly involved in the process of batch management [p.4, ¶ 4], as in claim 1. Also

disclosed are protocols for controlling identification comprising a new cellular identification, handing-over in suspension of the lymphocytes or monocytes in a culture medium, checking operations of quality (i.e. checking for annihilation of antibodies), and a re-use of the lymphocytes in the patient [p.4, ¶ 2], as in claims 1, 17, and 18. Lefesvre teach gene therapy protocols [p.2, ¶ 12], as in claim 15, a plurality of sites of cryogenic storage designed to receive the batches of immuno-qualified cells [p.3, ¶ 2], as in claim 16. Lefesvre also teach taking blood from a patient, a treatment of taken blood and a separation of the lymphocytes and/or monocytes, a cellular identification, a fractionation to carry out a whole of batches of lymphocytes and/or monocytes, a preparation of the lymphocytes and/or monocytes, including dehydration, grouping and setting in cryogenic storage of N batches of lymphocytes and/or monocytes [p.3, ¶ 9], as in claims 18 and 20. Claims 32-34 are newly added and therefore rejected as necessitated by amendment.

Response to Arguments

Applicant's arguments, filed 11/16/2007, that LEFESVRE does not disclose the steps of collecting, during successive collections or batches, information that characterizes the status of health and/or the physiological status of said human or animal subject have been considered but are not persuasive. Claim 1 recites "during successive collections or batches, collecting information characteristic of the status of health and/or psychological status…". Lefesvre et al. a shows a method and system for managing immunocompetent cell batches belonging to a human subject from whom said sets have been removed for future use on said subjects or relatives. The process of management of batches of immuno-qualified cells includes [p.2, ¶2] conditioning (i.e. processing) and a storage of the batches of immuno-qualified cells in one or more centers of storage, and enrichment (i.e. processing) of a personal library of immuno-qualified cells starting from the successively taken batches, this personal library preserving a sum of immunizing information stored in the taken immuno-qualified cells. Additionally, Figure 1 shows

a system for preserving cells (e.g. deep freezing) comprising multiple storage centers for storing batch information, steps for obtaining patient data (i.e. identification), and steps for storing data comprising lymphocyte data from multiple batches. Therefore, Lefesvre shows collecting information that is characteristic of the status of health of a subject during "successive" collections or batches, and provides at least one teaching for processing measurements made on samples.

Applicant's arguments, filed 11/16/2007, that LEFESVRE does not disclose that such status-characterizing information could be obtained by processing measurements made on samples of blood and/or fluid and secretions and/or hair collected from said human or animal subject, or that such status-characterizing information gathering could be effected before or during the immunocompetent cells collection. Claim 1 recites "said status-characterizing information being obtained by processing measurements made on samples selected from the group consisting of blood, fluid, ...". Lefesvre shows obtaining blood from a patient, a treatment of taken blood and a separation of the lymphocytes and/or monocytes, a cellular identification, a fractionation to carry out a whole of batches of lymphocytes and/or monocytes, a preparation of the lymphocytes and/or monocytes, including dehydration, grouping and setting in cryogenic storage of N batches of lymphocytes and/or monocytes [p.3, ¶ 9]. For these reasons, and those set forth above, Lefesvre shows information that could be obtained by processing measurements on samples of blood and/or fluid.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 15-18, 20, 21, 25, and 30-34 are rejected under 35 U.S.C. 103(a) as being made obvious by Lefesvre et al. (WO/1999/053030; Publication Date: 10/21/1999, p.1-5), in view of Cha et al. (Physiol. Meas., 1994, Vol. 15, p. 129-137). Claims 32-34 are newly added and rejected as necessitated by amendment.

Lefesvre et al. teach a method and system for management of batches of immuno-qualified cells, in particular of lymphocytes (i.e. immunocompetent cells) or monocytes, for differed uses [Abstract], as set forth above and applied to claims 1, 4, 15-19, 20, 25, and 30-33.

Lefesvre et al. do not specifically bioelectronic information collected from blood, as in claims 2, 21, and 34.

Cha et al. teach an electronic method for obtaining bioelectronic information by processing previously collected patient blood samples. Cha et al. specifically teach obtaining resistance (i.e. resistivity) and reactance values [Abstract], as in claims 2, 21, and 34.

It would have been obvious to some one of ordinary skill in the art at the time of the instant invention to use the method for managing immunocompetent cell batches taught by Lefesvre in combination with the bioelectric method taught by Cha et al., since Lefesvre shows the collection of blood and processing of blood to obtain information related to patient health, above. One of ordinary skill in the art would have been motivated to combine the above references in order to improve the accuracy of patient blood sample measurements as suggested by Cha et al. [p.136, ¶ 3and 4], resulting in the practice of the instant invention with predictable results.

Response to Arguments

Applicant's arguments, filed 11/16/2007, that LEFESVRE does not disclose the steps of collecting, during successive collections or batches, information that characterizes the status of health and/or the physiological status or deferred use protocols have been considered but are not persuasive. Regarding steps for collecting, during successive collections or batches, this issue has been addressed above. Regarding the issue of deferred use protocols, the invention of Lefesvre et al. concerns a method for managing immunocompetent cell batches belonging to human subject from whom said sets have been removed for future use on said subjects or relatives. Lefesvre also shows a process comprising a plan of taking away of the batches of immuno-qualified cells with various stages of the life of each human subject and predetermined ages of the human subject. Therefore, Lefesvre shows collecting information that is characteristic of the status of health of a subject during "successive" collections or batches, and provides at least one teaching for deferred use protocols.

Applicant's applicant's regarding the Barnhill and Schettler et al. are moot in view of the cancellation of claims 4-5, 8-10, 19, and 23-24.

Obviousness Type Double Patenting

The non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 C.F.R. 1.321 (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. 3.73(b).

Claim 1 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 7 of U.S. Patent No. 6,415,201 (Issued Jul. 2, 2002) in view of Lefesvre et al. (WO/1999/053030; Publication Date: 10/21/1999, p.1-5). The instant claims and those of US 6,415,201 both are directed to methods and system for managing batches of cells collected from subjects for deferred use, with minor variations. US 6,415,201 shows the collection of batches of components of the haemopoietic system, and are therefore generic to instant claims. US 6,415,201 does not show the collection of immunity information or health status information for immunocompetent cells. Lefesvre et al. shows the collection and processing of status characterizing information (i.e. blood) for immunocompetent cells, and shows processing blood to obtain information related to patient health. It would have been obvious to one of ordinary skill in the art at the time of the instant invention to practice

the system for managing batches of cells as taught by US 6,415,201 to collect immunity information for managing immunocompetent cell batches in view of Lefesvre et al. (WO/1999/053030; Publication Date: 10/21/1999, p.1-5), since components of the haemopoietic system include immunocompetent cells.

Response to Arguments

Applicant's arguments, filed 11/16/2007, have not addressed non-statutory double patenting rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached at 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Pablo S. Whaley/

Patent Examiner

Art Unit 1631

/John S. Brusca/
Primary Examiner, Art Unit 1631